UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

OTSUKA PHARMACEUTICAL CO., LTD.,	:	**Civil Action No. 07-1000(MLC)**
Plaintiff/Counter-Defendant,	:	
v.	:	
APOTEX CORP. and APOTEX INC.,	:	**MEMORANDUM OPINION**
Defendants/Counter-Plaintiffs.	:	

HUGHES, U.S.M.J.

I. INTRODUCTION

This matter comes before the Court upon Motion by Defendant Apotex Inc. ("Apotex") for a Protective Order Preventing the deposition of Apotex's Chief Executive Officer Dr. Barry Sherman ("Dr. Sherman") [dkt. entry no. 138], returnable September 2, 2008. Plaintiff Otsuka Pharmaceutical Co., Ltd. ("Otsuka") opposed the motion on August 21, 2008. [dkt. entry no. 143]. Defendant filed a reply brief on August 28, 2008. [dkt. entry no. 150]. The issue is whether Dr. Sherman must appear for a deposition. The Court heard oral argument on September 11, 2008. For the reasons stated herein, Defendant's Motion is denied.

II. BACKGROUND AND PROCEDURAL HISTORY

Otsuka alleges that Apotex committed patent infringement with respect to U.S. Patent No. 5,006,528. "[T]he alleged act of infringement is the technical act of Apotex's filing an abbreviated new drug application (ANDA) with the Food and Drug Administration (FDA) to manufacture and sell a generic version of Otsuka's aripiprazole drug product." (Def.'s Br. at 2.) This motion specifically addresses whether Dr. Sherman must submit to a deposition.

On March 10, 2008, Otsuka served a Rule 30(b)(6) notice seeking Apotex's corporate testimony on a number of topics. (Pl.'s Opp'n Br. at 9.) Apotex produced the President of

Apotex Corp. and Apotex's Director of Regulatory Affairs, both of whom respectively disclosed that Dr. Sherman heads the product selection team, which in turns selects the drug products that Apotex will develop as generics, which is most likely what occurred with aripiprazole and that Dr. Sherman determines whether to make a paragpraph IV certification, and did so with respect to aripiprazole. (*See* Pl.'s Opp'n Br. Ex. 4 and Ex. 5.)

On August 11, 2008, Apotex filed the present Motion for a Protective Order to prevent the deposition of Dr. Sherman [dkt. entry no. 138]. The Motion was opposed on August 21, 2008 [143]. Subsequently, Apotex filed a reply brief on August 28, 2008 [dkt. entry no. 150].

A. Defendant's Arguments in Support of the Motion for a Protective Order

Defendant makes three arguments why the Motion for a Protective Order should be granted. Specifically, Defendant argues that (1) Dr. Sherman's deposition is not necessary for Otsuka to develop its infringement case; (2) Dr. Sherman's deposition is not necessary for Otsuka to defend agaisnt Apotex's allegations of patent invalidity and unenforceability; and (3) other courts routinely prohibit or severely restrict the scope of depositions of the other side's chief executive officers, unless they have unique, highly relevant knowledge that cannot be obtained through other witnesses. (Def.'s Br. at 2, 4 and 9.)

Defendant argues that the Federal Circuit has held that the paper ANDA record controls the infringement analysis. The Federal Circuit has stated that

> Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry.

See Def.'s Br. at 3 (citing *Abbott Labs*. v. *TorPharm, Inc*., 300 F.3d 1367, 1373 (Fed. Cir. 2002)). Upon this backdrop, Defendant also contends that "Apotex already has produced its ANDA to Otsuka [and] [a]ll relevant and necessary information pertaining to Apotex's proposed

generic product is contained therein" (Def.'s Br. at 3.) Defendant claims that "Otsuka has not alleged willful infringement [and], even if it did, case law firmly establishes that the mere filing of an ANDA, which is all that Apotex did here, is not sufficient to support a willfulness claim. Therefore, Apotex's motivation for filing its ANDA is not relevant to infringement nor relevant in order to depose Dr. Sherman on this subject." (Def.'s Br. at 4, citing *Glaxo Group Ltd*. v. *Apotex, Inc*., 376 F.3d 1339, 1350-51 (Fed. Cir. 2004)).

Defendant argues that Dr. Sherman has no unique or discoverable information that is relevant to Apotex's allegations that Otsuka's patent is invalid and unenforceable. (Def.'s Br. at 4.) Defendant represents that "Dr. Sherman will not testify at trial in support of Apotex's invalidity and unenforceability defense, and Otsuka can discover the bases of those defense from Apotex's experts and from contention interrogatory responses." *Id*. Defendant recognizes that there are four underlying factual determinations for obviousness with the fourth being objective indicia of nonobviousness. *See* Def.'s Br. at 5; *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1377 (Fed. Cir. 2006). Defendant contends that "Otsuka is likely to assert that Dr. Sherman has knowledge pertaining to objective indicia of obviousness, including the alleged copying and alleged commercial success of Otsuka's ariprazole product." *Id*. Upon that assumption, Defendant argues that "a showing of copying is only equivocal evidence of non-obviousness in the absence of a more compelling objective indicia of other secondary considerations." (Def.'s. Br. at 6) (citing *Ecolochem, Inc*. *v*. *Southern California Edison Co*., 227 F.3d 1361, 1380 (Fed. Cir. 2000)). Defendant concedes that "even if copying evidence were somehow relevant to this case, Apotex's ANDA sets forth what Apotex did in developing its generic aripiprazole product; [therefore,] Dr. Sherman's deposition is not necessary to determine

the makeup of Apotex's contemplated generic product." (Pl.'s. Br. at 7.) Defendant argues that commercial success is not relevant to this case and states that "[t]he Federal Circuit has stated on several occasions that commercial success is not probative of nonobviousness unless there is a nexus between the commercial success and the thing patented." *Id*. (*See also Syntex (U.S.A.) LLC v. Apotex*, *Inc*., 407 F.3d 1371 (Fed. Cir. 2005); *Merck & Co. v. Teva Pharm.,* 395 F.3d 136, 1376-77 (Fed. Cir. 2005)). Defendant represents that Otsuka previously listed another patent (now expired U.S. Pat. No. 4,734,416) in the FDA Orange Book as covering its aripiprazole product. (Def.'s Br. at 8.) Defendant also represents that this patent had broader claims than the patent in suit, and until its expiration would have kept competitors from developing their own version of aripiprazole; therefore, discovery relating to Dr. Sherman's knowledge of whether Otsuka's aripoprazole was commercially successful is unnecessary. *Id*.

Defendant argues that although Dr. Sherman signed the Paragraph IV letter stating that the patent-in-suit is unenforceable and that its claims are invalid and not infringed by Apotex, he did not draft the letter and does not have discoverable information relating to its contents. *Id*. Defendant further argues that a Chief Executive Officer of a corporation does not have personal knowledge or relevant information pertaining to the contents of a letter merely because he or she signs the letter. *Id*. Defendant represents that Dr. Sherman did not draft the Paragraph IV letter, but merely signed it on behalf of Apotex, Inc. *Id.*

Lastly, Defendant argues that Dr. Sherman does not have unique knowledge that is relevant to any issue in this case and that any probative value to Dr. Sherman's testimony is far outweighed by the burden of having to produce him on topics on which other employees have equal or greater knowledge and already have testified. *Id*. at 9-10; *see also Salter v. Upjohn Co*.,

593 F.2d 649, 651 (5th Cir. 1979) (a protective order was necessary to prevent the deposition of Defendant's President in light of reasonable assertions that the President did not have any direct knowledge of the facts); *Baine v. General Motors Corp*., 141 F.R.D. 332, 334 (M.D. Ala. 1991) (denying the plaintiff's request to depose a corporate vice president who lacked unique personal knowledge of the issues). Defendant represents that Otsuka already deposed Apotex's 30(b)(6) witnesses on the same topics it wishes to depose Dr. Sherman, which are in any event irrelevant to the issues to be decided in this case; therefore, the court should issue a protective order preventing the deposition of Dr. Sherman. (Def.'s Br. at 10.)

B. Plaintiff's Argument Opposing the Motion for a Protective Order

In opposition, Plaintiff sets forth four arguments why the Defendant's Motion for a Protective Order should be denied. Specifically, Plaintiff argues that (1) Dr. Sherman is intimately involved in the business of Apotex, including the accused aripiprazole products; (2) Dr. Sherman has unique, discoverable information that is relevant to the claims and defense Apotex has raised in this litigation; (3) Dr. Sherman's knowledge is not cumulative of that of other Apotex witnesses; and (4) Dr. Sherman has been deposed or testified at trial in many cases. (Pl.'s Opp'n at 1, 10.)

Plaintiff argues that Dr. Sherman is not a hands off CEO removed from the actual business, but rather Dr. Sherman is intimately involved in virtually all substantive business decisions that Apotex makes and the design of its products, specifically the accused aripiprazole products. *Id*. at 2-3. Plaintiff further argues that many courts have found that Dr. Sherman is responsible for selecting the products that Apotex will develop and market. (Pl.'s Br. at 3; *see also Glaxo Group Ltd. V. Apotex, Inc.*, 268 F. Supp. 2d 1013, 1023 (N.D. Ill. 2003), *aff'd in part,*

rev'd in part, 2004 U.S. App. LEXIS 15489 (Fed. Cir. 2004)). For example, in the case at bar the decision to develop a generic version of Otsuka's Abilify® was made by the product selection team at Apotex, which is headed by Dr. Sherman. (*See* Pl.'s Opp'n Br. Ex. 4, McIntire Dep. at 82:7-14.) Another example, of Dr. Sherman playing a key role in Apotex's aripiprazole products at issue in this case is evidenced by his decision to make and sign a paragraph IV certification notice letter. (*See* Pl.'s Br. at 4; *see also* Pl.'s Ex. 6.) Plaintiff further argues, "while Apotex suggests that CEOs often sign documents they do not understand (Apotex Br. at 8), Apotex was careful not to state that Dr. Sherman has no knowledge concerning the contents of Apotex's paragraph IV notice letter. (Pl.'s Br. at 4.)

With regards to Apotex's claim that Dr. Sherman's deposition is not necessary for Otsuka to defend against Apotex's allegations of patent invalidity and unenforceability, Otsuka contends that the questions is not whether Dr. Sherman deposition is necessary to win the case, but rather whether Dr. Sherman has relevant, discoverable information concerning any of the claims and defenses in the case. *Id*. at 5. Plaintiff further contends that neither expert depositions nor contention interrogatory responses are a substitute for Dr. Sherman's deposition, nor do they preclude the use of a Rule 30(b)(1) deposition as a proper discovery tool. *Id*. at 6. Plaintiff argues that Otsuka is entitled to discover the factual bases for the assertions Dr. Sherman made in his paragraph IV notice letter because the facts themselves are not privileged. *Id*. Plaintiff further argues that Apotex cannot deny them full discovery on unexpected properties and objective indicia of non-obviousness. *Id*. at 7. Because Dr. Sherman headed the group at Apotex that decided to copy Otsuka's Abilify®, he is very likely to have information relevant to the

commercial success, industry acclaim and long felt need for the product, as well as the unique properties of the drug; therefore, Otsuka argues they should be able to depose him. *Id*.

Plaintiff argues that Apotex ignores the questions of long felt need and industry acclaim and aripirprazole's unexpected properties because it cannot explain the ten pages dedicated to the subject in the paragraph IV notice letter and instead argues that evidence of copying or commercial success is per se irrelevant and immune from discovery in ANDA cases. *Id*. at 7-8. Plaintiff further argues that "the decisions in *Aventis*, *Cable Electric, Ecolochem* and *Medpointe* do not hold that evidence of copying is irrelevant or immune from discover in an ANDA case. Similarly, neither *Merck v. Teva* nor *Syntex* held that evidence of commercial success was *per se* irrelevant or immune from discovery. *Id.* at 9. Plaintiff is not requesting the Court to rule on the question of validity or admissibility of any evidence it might develop concerning objective indicia of non-obviousness, but merely requesting an opportunity to discover the facts in the first place. *Id*.

In response to Apotex's argument that Dr. Sherman's knowledge is cumulative of information Otsuka has obtained or can obtain from other deponents, Plaintiff contends that this is inaccurate. *Id*. Plaintiff contends in response to the March 10, 2008 Rule 30(b)(6) notice seeking Apotex's corporate testimony on a number of topics, Apotex produced individuals who were unable to provide testimony on both the full scope of information that Apotex considered in making the decision to pursue aripiprazole and on the factual bases underlying the assertions in the Paragraph IV notice letter. *Id*. at 10.

Lastly, Plaintiff argues that the request for Dr. Sherman's deposition is not extraordinary. *Id*. Plaintiff argues that Dr. Sherman has been deposed or testified at trial in numerous litigations

concerning Apotex's generic products because of his hands on management style and intimate involvement in Apotex's business. *Id*. Plaintiff further argues that the courts have held that "highly-placed executives are not immune from discovery [,and] 'the fact that [an executive] has a busy schedule' cannot shield that witness from being deposed." *See id.* at 11 (citing *Six West Retial Acquisition, Inc. v. Sony Mgt. Corp.*, 203 F.R.D. 98, 102-4 (S.D.N.Y. 2001)). Therefore, the motion for a protective order should be denied.

III. DISCUSSION

Federal Rule of Civil Procedure 26(b)(2)(C) provides that discovery can be limited if it is "unreasonably cumulative or duplicative" or obtainable from a more convenient, less burdensome, or less expensive source; "the party seeking discovery has had ample opportunity to obtain the information by discovery in the action;" or the proposed discovery's burden or expense outweighs its likely benefit. FED. R. CIV. P. 26(b)(2)(C). Apotex maintains that they do not intend to call Dr. Sherman as a witness at trial and the relevant subject matter on which Otsuka seeks to depose him on can be obtained from other witnesses, and therefore to depose Dr. Sherman would be unnecessary. (*see* Def.'s Br. at 2.) However, Otsuka has demonstrated that Dr. Sherman has unique knowledge relating to the formulation of Apotex's claims and defenses in this litigation, the basis for Apotex filing an ANDA for a generic version of Abilify® and the factual bases underlying Apotex's paragraph IV notice letter that is not obtainable from alternate sources. (*see* Pl.'s Opp'n Br. at 4-5; *see also* Pl.'s Opp'n Br. Ex. 4 and Ex. 5.) More specifically, Dr. Sherman not only heads the product selection team, which selects the drug products that Apotex will develop as generics, but he also determines whether to make a paragpraph IV certification, and did so with respect to aripiprazole. (*See* Pl.'s Opp'n Br. Ex. 4

and Ex. 5.) Moreover, in *Glaxo Group Ltd. v. Apotex, Inc*., Apotex stipulated that "Dr. Sherman decides what drugs Apotex will develop and market based on their historic sales levels, and whether he can design around the various barriers in order to bring the product to market . . ." *Glaxo Group Ltd.*, 268 F. Supp. 2d 1013,1023 (N.D. Ill. 2003). Additionally, the paragraph IV notice letter signed by Dr. Sherman alleges instances of inequitable conduct and this factor alone would justify the deposition of Dr. Sherman.

Furthermore, multiple jurisdictions recognize that there is not a protective blanket that prohibits discovery from highly-placed executives. *See Six West Retail Acquisition, Inc. v. Sony Mgt. Corp.,* 203 F.R.D. 98, 102-4 (S.D.N.Y. 2001) (allowing deposition of Sony's chairman who monitored the corporate policy underlying the suit, and several prior depositions had proved fruitless); *see also General Star Indemnity Co. v. Platinum Indemnity Ltd.*, 210 F.R.D. 80 (S.D.N.Y. 2002) (allowing depositions of two high level executives of the plaintiff company where the executives had unique personal knowledge of the facts relating to company policies underlying the case). Dr. Sherman has been deposed or testified at trial before the instant litigation because of his hands on management style. *See*, *e.g.*, *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1040 (Fed. Cir. 2001); *Glaxo Group Ltd. v. Apotex, Inc*., 268 F. Supp. 2d 1013, 1033 (N.D. Ill. 2003); *In re Omeprazole Patent Litigation*, 409 F. Supp. 2d 381, 473 (S.D.N.Y. 2007). Therefore, the Court is denying the Motion for a Protective Order pursuant to FED. R. CIV P. 26(c), regardless of any alleged undue burden deposing Dr. Sherman would create, because Dr. Sherman has unique knowledge that the other FED. R. CIV P. 30(b)(6) witnesses Apotex has produced have been unable to provide.

IV. CONCLUSION

For the reasons stated herein, Defendant's Motion for a Protective Order to Prevent the Deposition of Apotex's CEO Dr. Barry Sherman [138] is denied. An appropriate order accompanies this Memorandum Opinion.

DATED: September 12, 2008.